

SUBCHAPTER A—GENERAL PROVISIONS

PART 400—INTRODUCTION; DEFINITIONS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

Subpart A [Reserved]

Subpart B—Definitions

§ 400.200 General definitions.

In this chapter, unless the context indicates otherwise—

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).

ALJ stands for administrative law judge.

Area means the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

CMP stands for competitive medical plan.

Conditions of participation includes requirements for participation as the latter term is used in part 483 of this chapter.

Condition level deficiencies includes deficiencies with respect to “level A requirements” as the latter term is used in parts 442 and 483 of this chapter.

CORF stands for comprehensive outpatient rehabilitation facility.

CFR stands for Code of Federal Regulations.

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

CY stands for calendar year.

DAB stands for Departmental Appeals Board.

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

ESRD stands for end-stage renal disease.

FDA stands for the Food and Drug Administration.

FQHC means Federally qualified health center.

FR stands for FEDERAL REGISTER.

FY stands for fiscal year.

HCPP stands for health care prepayment plan.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

ICF/MR stands for intermediate care facility for the mentally retarded.

Medicaid means medical assistance provided under a State plan approved under title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under title XVIII of the Act.

NCD stands for national coverage determination.

OASDI stands for the Old Age, Survivors, and Disability Insurance program under title II of the Act.

OIG stands for the Department's Office of the Inspector General.

QDWI stands for Qualified Disabled and Working Individual.

QIO stands for quality improvement organization.

QMB stands for Qualified Medicare Beneficiary.

Qualified Disabled and Working Individual means an individual who—

(1) Is eligible to enroll for Medicare Part A under section 1818A of the Act.

(2) Has income, as determined in accordance with SSI methodologies, that does not exceed 200 percent of the Federal poverty guidelines (as defined and revised annually by the Office of Management and Budget) for a family of the size of the individual's family;

(3) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the relevant maximum amount established, for SSI eligibility, for an individual or for an individual and his or her spouse; and

(4) Is not otherwise eligible for Medicaid.

Qualified Medicare Beneficiary means an individual who—

(1) Is entitled to Medicare Part A, with or without payment of premiums, but is not entitled solely because he or she is eligible to enroll as a QDWI;

(2) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the maximum amount established for SSI eligibility; and

(3) Has income, as determined in accordance with SSI methodologies, that does not exceed 100 percent of the Federal poverty guidelines.

Quality improvement organization means an organization that has a contract with CMS, under part B of title XI of the Act, to perform utilization and quality control review of the health care furnished, or to be furnished, to Medicare beneficiaries.

Regional Administrator means a Regional Administrator of CMS.

Regional Office means one of the regional offices of CMS.

RHC stands for rural health clinic.

RRB stands for Railroad Retirement Board.

Secretary means the Secretary of Health and Human Services.

SNF stands for skilled nursing facility.

Social security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

SSA stands for Social Security Administration.

United States means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Is-

lands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

[48 FR 12534, Mar. 25, 1983, as amended at 49 FR 7206, Feb. 27, 1984; 50 FR 15326 and 15358, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985; 51 FR 43197, Dec. 1, 1986; 52 FR 27764, July 23, 1987; 56 FR 8852, Mar. 1, 1991; 56 FR 38077, Aug. 12, 1991; 57 FR 24975, June 12, 1992; 57 FR 55912, Nov. 25, 1992; 63 FR 35065, June 26, 1998; 63 FR 52611, Oct. 1, 1998; 63 FR 68690, Dec. 14, 1998; 66 FR 39452, July 31, 2001; 67 FR 36540, May 24, 2002]

§ 400.202 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

Beneficiary means a person who is entitled to Medicare benefits.

Carrier means an entity that has a contract with CMS to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

Critical access hospital (CAH) means a facility designated by HFCA as meeting the applicable requirements of section 1820 of the Act and of subpart F of part 485 of this chapter.

Entitled means that an individual meets all the requirements for Medicare benefits.

Essential access community hospital (EACH) means a hospital designated by CMS as meeting the applicable requirements of section 1820 of the Act and of subpart G of part 412 of this chapter, as in effect on September 30, 1997.

GME stands for graduate medical education.

Hospital insurance benefits means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of title XVIII of the Act.

Intermediary means an entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

Medicare Part A means the hospital insurance program authorized under Part A of title XVIII of the Act.

Medicare Part B means the supplementary medical insurance program authorized under Part B of title XVIII of the Act.

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service, that makes under section 1862(a)(1) of the Act, and publishes as a FEDERAL REGISTER notice or CMS Ruling. (The term does not include coverage changes mandated by statute.)

Nonparticipating supplier means a supplier that does not have an agreement with CMS to participate in Part B of Medicare in effect on the date of the service.

Participating supplier means a supplier that has an agreement with CMS to participate in Part B of Medicare in effect on the date of the service.

Payment on an assignment-related basis means payment for Part B services—

(1) To a physician or other supplier that accepts assignment from the beneficiary, in accordance with § 424.55 or § 424.56 of this chapter;

(2) To a physician or other supplier after the beneficiary's death, in accordance with § 424.64(c)(1) of this chapter; or

(3) To an entity that pays the physician or other supplier under a health benefit plan, in accordance with § 424.66 of this chapter.

Provider means a hospital, a CAH, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Railroad retirement benefits means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, CAH, or SNF facilities.

Supplementary medical insurance benefits means payment to or on behalf of an entitled individual for services cov-

ered under Part B of title XVIII of the Act.

Supplier means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.

[48 FR 12534, Mar. 25, 1983, as amended at 48 FR 56024, Dec. 16, 1983; 49 FR 3658, Jan. 30, 1984; 51 FR 43197, Dec. 1, 1986; 52 FR 27764, July 23, 1987; 55 FR 24567, June 18, 1990; 56 FR 8852, Mar. 1, 1991; 58 FR 30666, May 26, 1993; 59 FR 6576, Feb. 11, 1994; 60 FR 63175, Dec. 8, 1995; 62 FR 46025, Aug. 29, 1997; 62 FR 59098, Oct. 31, 1997; 63 FR 35065, June 26, 1998]

§ 400.203 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

Applicant means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

Federal financial participation (FFP) means the Federal Government's share of a State's expenditures under the Medicaid program.

FMAP stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

Medicaid agency or *agency* means the single State agency administering or supervising the administration of a State Medicaid plan.

Nursing facility (NF), effective October 1, 1990, means an SNF or an ICF participating in the Medicaid program.

PCCM stands for primary care case manager.

PCP stands for primary care physician.

Provider means either of the following:

(1) For the fee-for-service program, any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

(2) For the managed care program, any individual or entity that is engaged in the delivery of health care services and is legally authorized to do

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so by the State in which it delivers the services.

Recipient means an individual who has been determined eligible for Medicaid.

Services means the types of medical assistance specified in section 1905(a) of the Act and defined in subpart A of part 440 of this chapter.

State means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State plan or the plan means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administration of a Medicaid program in accordance with Federal requirements.

[48 FR 12534, Mar. 25, 1983, as amended at 50 FR 33029, Aug. 16, 1985; 56 FR 8852, Mar. 1, 1991; 57 FR 29155, June 30, 1992; 67 FR 41094, June 14, 2002]

Subpart C—OMB Control Numbers for Approved Collections of Information

SOURCE: 49 FR 4477, Feb. 7, 1984, unless otherwise noted.

§ 400.300 Scope.

This subpart collects and displays control numbers assigned by the Office of Management and Budget (OMB) to collections of information contained in CMS regulations, in accordance with OMB's regulations for controlling paperwork burdens on the public, 5 CFR part 1320. CMS intends that the subpart comply with the requirements of section 3507(f) of the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35 which requires that agencies shall not engage in a "collection of information" without obtaining a control number from OMB.

§ 400.310 Display of currently valid OMB control numbers.

| Sections in 42 CFR that contain collections of information | Current OMB control Nos. |
|---|--------------------------|
| 403.510 | 0938—0641 |
| 405.509 | 0938—0666 |
| 405.512 | 0938—0008 |
| 405.2112, 405.2123, 405.2134, 405.2136–405.2140, 405.2171 | 0938—0386 |

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| Sections in 42 CFR that contain collections of information | Current OMB control Nos. |
|--|-------------------------------|
| 409.43 | 0938—0365 |
| 410.105 | 0938—0267 |
| 411.25, 411.32 | 0938—0564 |
| 411.54 | 0938—0558 |
| 411.165 | 0938—0564 |
| 411.404, 411.406 | 0938—0465 |
| 411.408 | 0938—0566 |
| 412.42 | 0938—0666 |
| 412.92 | 0938—0477 |
| 412.105 | 0938—0456 |
| 412.230, 412.232, 412.234, 412.236, 412.254, 412.260, 412.266, 412.278 | 0938—0573 |
| 415.60 | 0938—0301 |
| 415.162 | 0938—0301 |
| 416.43 | 0938—0506 |
| 416.47 | 0938—0266 and 0938—0506 |
| 417.126 | 0938—0472 |
| 417.436, 417.801 | 0938—0610 |
| 418.22, 418.24, 418.28, 418.56, 418.58, 418.70, 418.74 | 0938—0302 |
| 418.30, 418.82, 418.83, 418.96, 418.100 | 0938—0475 |
| 418.96, 418.100 | 0938—0302 |
| 421.117 | 0938—0542 |
| 424.3 | 0938—0008 |
| 424.5, 424.7, 424.20 | 0938—0454 |
| 424.22 | 0938—0489 |
| 424.32, 424.34 | 0938—0008 |
| 431.17 | 0938—0467 |
| 431.50, 431.52, 431.55 | 0938—0247 |
| 431.107 | 0938—0610 |
| 431.306 | 0938—0467 |
| 431.625 | 0938—0247 |
| 431.630 | 0938—0445 |
| 431.800 | 0938—0247 |
| 431.806, 431.830, 431.432, 431.834, 431.836 | 0938—0438 |
| 432.50 | 0938—0459 |
| 433.36, 433.37 | 0938—0247 |
| 433.68, 433.74 | 0938—0618 |
| 433.110, 433.112–433.114, 433.116, 433.117, 433.119–433.121, 433.123, 433.127, 433.130, 433.131, 433.135 | 0938—0247 |
| 433.138 | 0938—0502 |
| | 0938—0553 and 0938—0555 |
| 433.139 | 0938—0459 |
| | 0938—0554 and 0938—0555 |
| 434.27 | 0938—0572 |
| 434.28 | 0938—0610 |
| 435.1, 435.910, 435.919, 435.920, 435.940, 435.945, 435.948, 435.952, 435.953, 435.955, 435.960, 435.965, 435.1003, 441.11, 441.15, 441.20 | 0938—0247 |
| 441.56, 441.58, 441.60, 441.61 | 0938—0354 |
| 441.302 | 0938—0449 |
| 441.303 | 0938—0272 and 0938—0449 |
| 441.351, 441.352, 441.353, 441.356, 441.365 | 0938—0613 |
| 442.505 | 0938—0366 |
| 447.31 | 0938—0287 |
| 447.45, 447.50, 447.51, 447.52 | 0938—0247 |
| 447.53 | 0938—0429 |
| 447.55 | 0938—0247 |
| 447.253 | 0938—0366 |
| | 0938—0523 and 0938—0556 |
| 447.255 | 0938—0193 |

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| Sections in 42 CFR that contain collections of information | Current OMB control Nos. |
|--|--------------------------|
| 447.272, 447.299 | 0938—0618 |
| 447.302, 447.331, 447.332, 447.333 | 0938—0247 |
| 456.80 | 0938—0247 |
| 456.654 | 0938—0445 |
| 456.700, 456.705, 456.709, 456.711, 456.712 | 0938—0659 |
| 462.102, 462.103 | 0938—0526 |
| 466.70, 466.72, 466.74 | 0938—0445 |
| 466.78 | 0938—0445 |
| | and |
| | 0938—0665 |
| 466.80, 466.94 | 0938—0445 |
| 473.18, 473.34, 473.36, 473.42 | 0938—0443 |
| 476.104, 476.105, 476.116, 476.134 | 0938—0426 |
| 481.61 | 0938—0328 |
| 482.12, 482.21, 482.22, 482.27, 482.30, 482.41, 482.43, 482.53, 482.56, 482.57, 482.60, 482.62 | 0938—0328 |
| 483.10 | 0938—0610 |
| 483.410, 483.420, 483.440, 483.460, 483.470 | 0938—0366 |
| 484.1, 484.2 | 0938—0365 |
| 484.10 | 0938—0365 |
| | and |
| | 0938—0610 |
| 484.12, 484.14, 484.16, 484.18, 484.30, 484.32, 484.34, 484.36, 484.48, 484.52 | 0938—0365 |
| 485.56, 485.58, 485.60, 485.64, 485.66 | 0938—0267 |
| | and |
| | 0938—0538 |
| 485.709, 485.711, 485.717, 485.719, 485.721, 487.723, 485.725, 485.727 | 0938—0336 |
| 486.104, 486.106, 486.110 | 0938—0338 |
| 486.155, 486.161, 486.163 | 0938—0336 |
| 488.10 | 0938—0646 |
| 488.18 | 0938—0667 |
| 488.26 | 0938—0646 |
| 489.20 | 0938—0564 |
| | and |
| | 0938—0667 |
| 489.24 | 0938—0334 |
| | 0938—0663 |
| | and |
| | 0938—0667 |
| 489.102 | 0938—0610 |
| 491.9, 491.10 | 0938—0334 |
| 493.35, 493.37, 493.39, 493.43, 493.45, 493.47, 493.49, 493.51, 493.53, | |
| 493.55, 493.60, 493.61, 493.62, 493.63 | 0938—0612 |
| 493.614, 493.633, 494.634 | 0938—0607 |
| 493.801—493.1285, 493.1425, 493.1701, 493.1703, 493.1705, 493.1707, 493.1709, 493.1711, 493.1713, 493.1715, 493.1717, 493.1719, 493.1721, 493.1775, 493.1776, 493.1777, 493.1780, 493.2001 | 0938—0612 |
| 494.52, 494.54, 494.56, 494.58, 494.64 | 0938—0608 |
| 498.22, 498.40, 498.58, 498.82 | 0938—0508 |
| 1004.40, 1004.50, 1004.60, 1004.70 | 0938—0444 |

[60 FR 50445, Sept. 29, 1995, as amended at 60 FR 63188, Dec. 8, 1995]

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

Subpart A [Reserved]

Subpart B—Confidentiality and Disclosure

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- 401.101 Purpose and scope.
401.102 Definitions.

- 401.105 Rules for disclosure.
401.106 Publication.
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401.116 Availability of records upon request.
401.118 Deletion of identifying details.
401.120 Creation of records.
401.126 Information or records that are not available.
401.128 Where requests for records may be made.
401.130 Materials available at social security district offices and branch offices.
401.132 Materials in field offices of the Office of Hearings and Appeals, SSA.
401.133 Availability of official reports on providers and suppliers of services, State agencies, intermediaries, and carriers under Medicare.
401.134 Release of Medicare information to State and Federal agencies.
401.135 Release of Medicare information to the public.
401.136 Requests for information or records.
401.140 Fees and charges.
401.144 Denial of requests.
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Subparts C–E [Reserved]

Subpart F—Claims Collection and Compromise

- 401.601 Basis and scope.
401.603 Definitions.
401.605 Omissions not a defense.
401.607 Claims collection.
401.613 Compromise of claims.
401.615 Payment of compromise amount.
401.617 Suspension of collection action.
401.621 Termination of collection action.
401.623 Joint and several liability.
401.625 Effect of CMS claims collection decisions on appeals.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh). Subpart F is also issued under the authority of the Federal Claims Collection Act (31 U.S.C. 3711).

Subpart A [Reserved]

Subpart B—Confidentiality and Disclosure

SOURCE: 46 FR 55696, Nov. 12, 1981, unless otherwise noted.

§ 401.101 Purpose and scope.

- (a) The regulations in this subpart: